K100824

SUZHOU KD Medical Appliance Co. Ltd.

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510(k) Summary

MAY 2 5 2010

Device

Trade name: DS 202-S manual wheelchair

Common name: Manual wheelchair

Classification name: Mechanical wheelchair

Medical specialty (Panel): Physical Medicine Device

Regulation number: 890.3850

Product Code: IOR

Classification: Class I

Predicate devices

HUADONG HD11 manual wheelchair (K082274)/Jiangyin East China Medical Technology Co., Ltd

Intend use of device

DS 202-S manual wheelchair is intended use to provide mobility to physically challenged persons limited to a sitting position on the flat and firm terrain in outdoor or indoor.

Device description:

DS 202-S manual wheelchair is intended use to provide mobility to physically challenged persons limited to a sitting position on the flat and firm terrain in outdoor and indoor. It consists of a rigid, mechanical and foldable steel frame and nylon upholstery back and seat. It has two 24" rear wheels and two 8" front casters for turning and maneuverability.

Substantial equivalence:

The **DS 202-S** manual wheelchair is substantially equivalent to the legal products. They have the same technological characteristics and intended use of the device.

Non-Clinical testing

The **DS 202-S** manual wheelchair meets the applicable performance requirements as specified in ANSI/RESNA WC Vol. 1 Sec. 1, Sec.5, Sec.7, Sec.8, Sec.15, Sec.16 and California Bureau of Home Furnishings 117.

Conclusion

The **DS 202-S** manual wheelchair shares performance features and technology with a device already legally marketed within the United States. Therefore, the **DS 202-S** manual wheelchair is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SUZHOU KD MEDICAL
% International Regulatory Consultant
Mr. Jacob Chang
16F-2 (16A) No. 462
SEC 2 Chongde RD BEUITUN DIST
Taichung
China (Taiwan) 406

MAY 25 2010

Re: K100824
Trade/Device Name: Manual Wheelchair, Model DS 202-S
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical wheelchair
Regulatory Class: I
Product Code: IOR
Dated: February 12, 2010
Received: March 24, 2010

Dear Mr. Chang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known): _____

Device Name: **Manual Wheelchair, Model DS 202-S**

Indications for Use:

DS 202-S manual wheelchair is intended use to provide mobility to physically challenged persons limited to a sitting position on the flat and firm terrain in outdoor and indoor.

Prescription Use _____ Over-the-Counter Use __X___

(Part 21 CFR 801 Subpart D) AND/OR

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE) Page 1 of 1

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(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number 

(Posted November 13, 2003)